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(52) UK CL (Edition V )

**A5R RGM**

(56) Documents Cited

**EP 0499077 A1**

**US 5498241 A**

**US 4941881 A**

**WO 2001/008740 A1**

**US 5171231 A**

(58) Field of Search

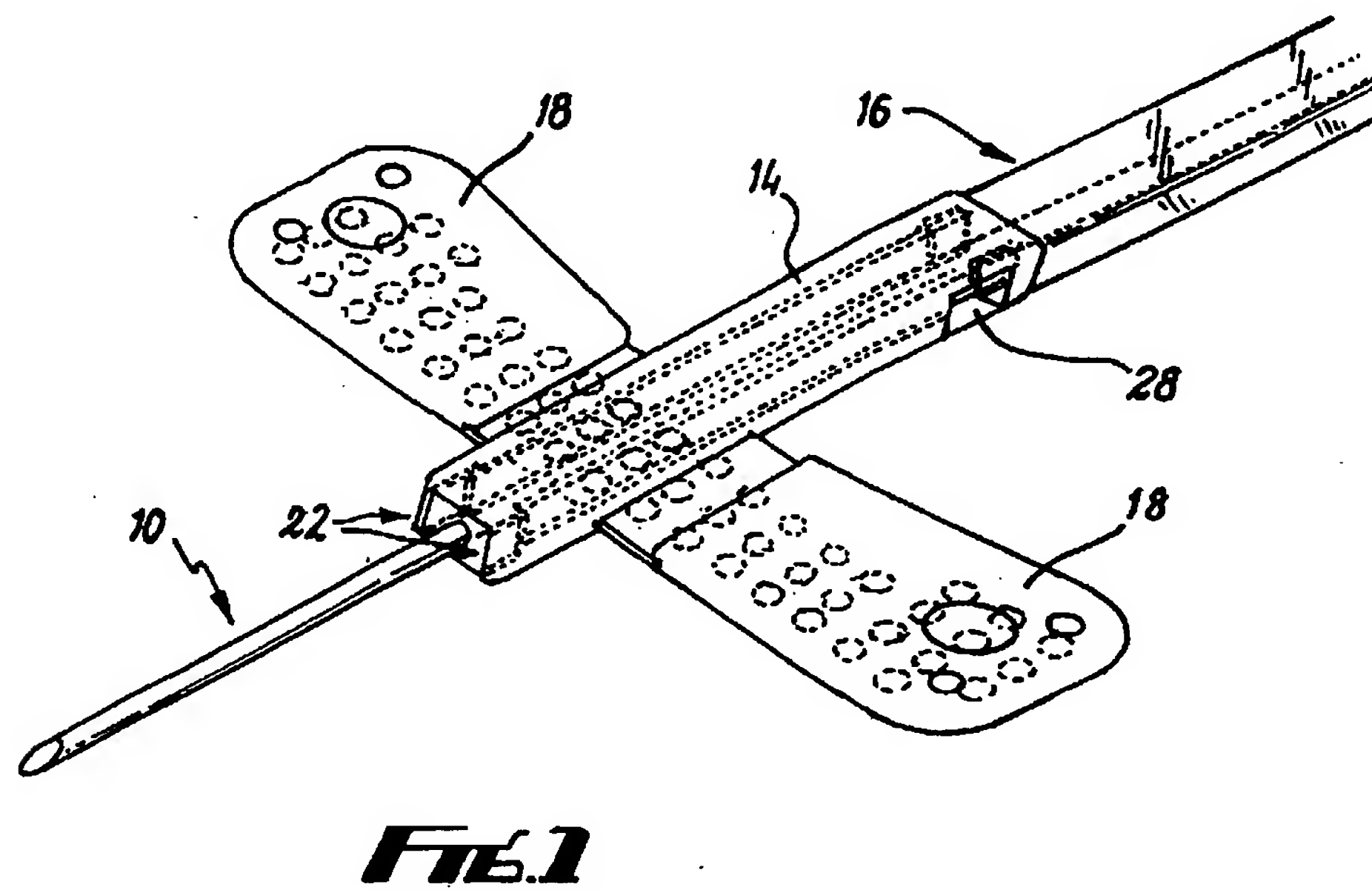
INT CL<sup>7</sup> **A61B 17/34, A61M 5/00 25/00**

Other: **ONLINE; EPODOC, WPI, JAPIO**

(54) Abstract Title

**CANNULA DEVICE WITH NON-ROTATABLE SAFETY SHEATH**

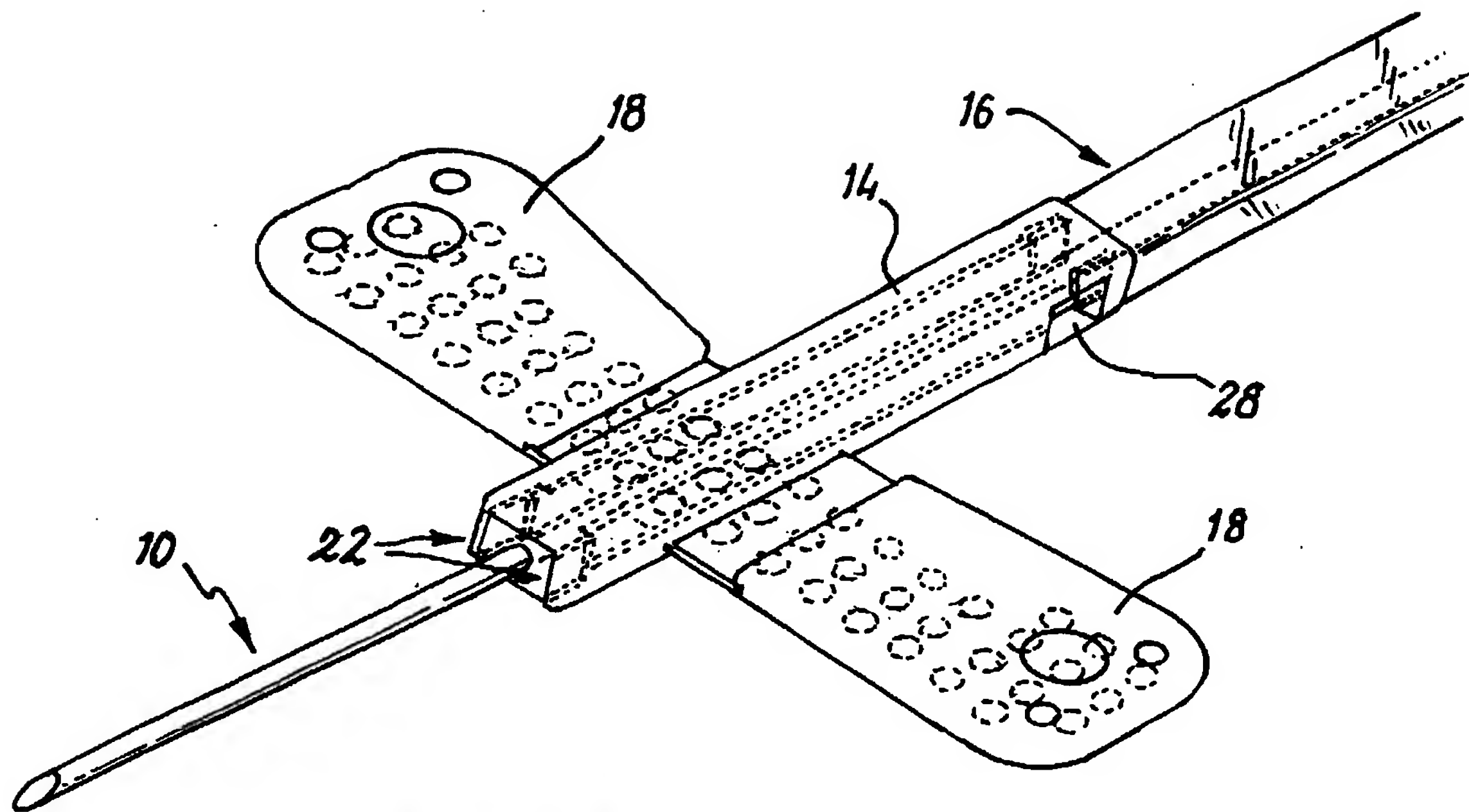
(57) A cannula device comprising a housing 14, a needle-mounting hub (12) which is axially slidable in the housing 14 and a flexible tube 16 extending from the housing 14 and in communication with the needle 10 to allow infusion and collection of fluids. The needle-mounting hub (12) is formed by a terminal portion of the flexible tubing 16. The hub (12) and housing 14 are of non-circular cross-section. Lugs 20 may be provided on the hub (12) to engage with recesses 22 and 28 in the housing 14 to hold the needle in retracted or extended positions. A window may be provided in the housing to view the needle in its retracted position and the housing and hub may be of different colours.



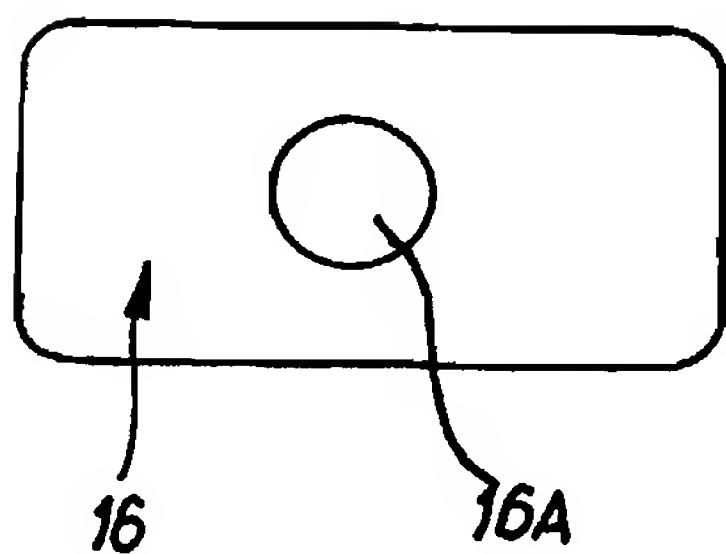
At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

The claims were filed later than the filing date but within the period prescribed by Rule 25(1) of the Patents Rules 1995.

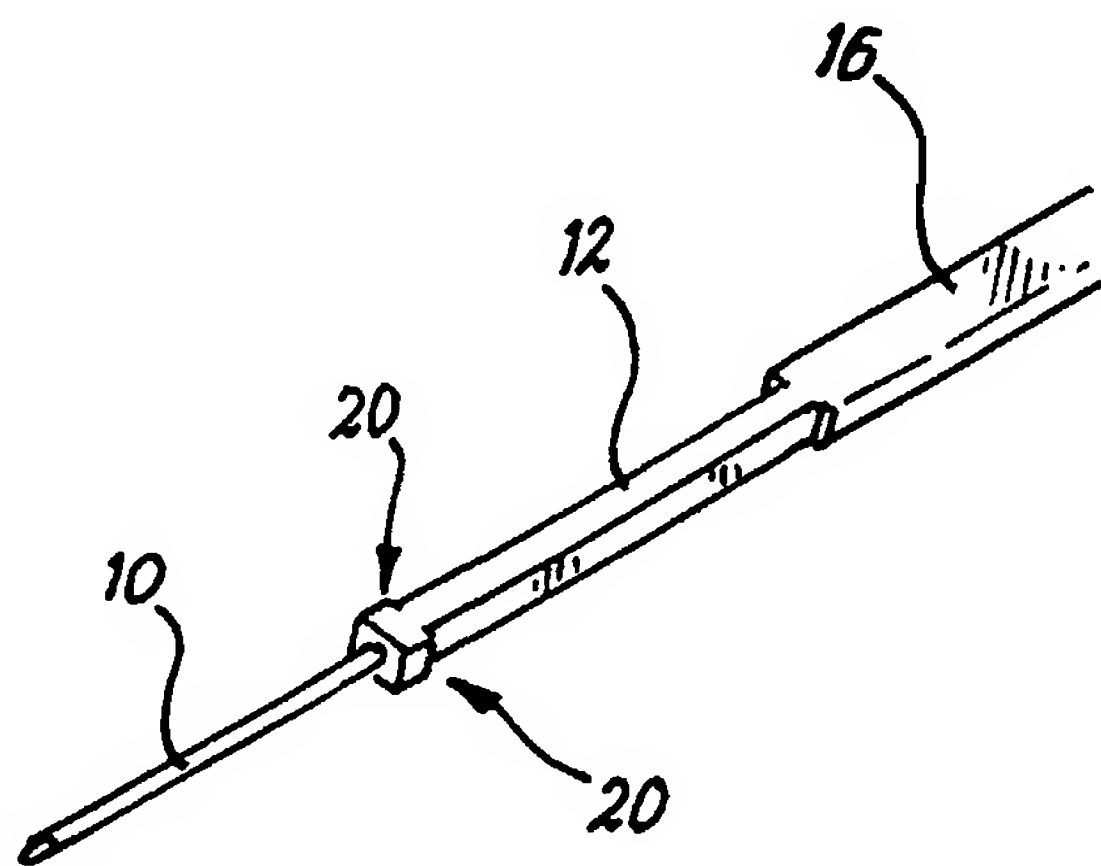
24 45 02  
1/2



**Fig. 1**



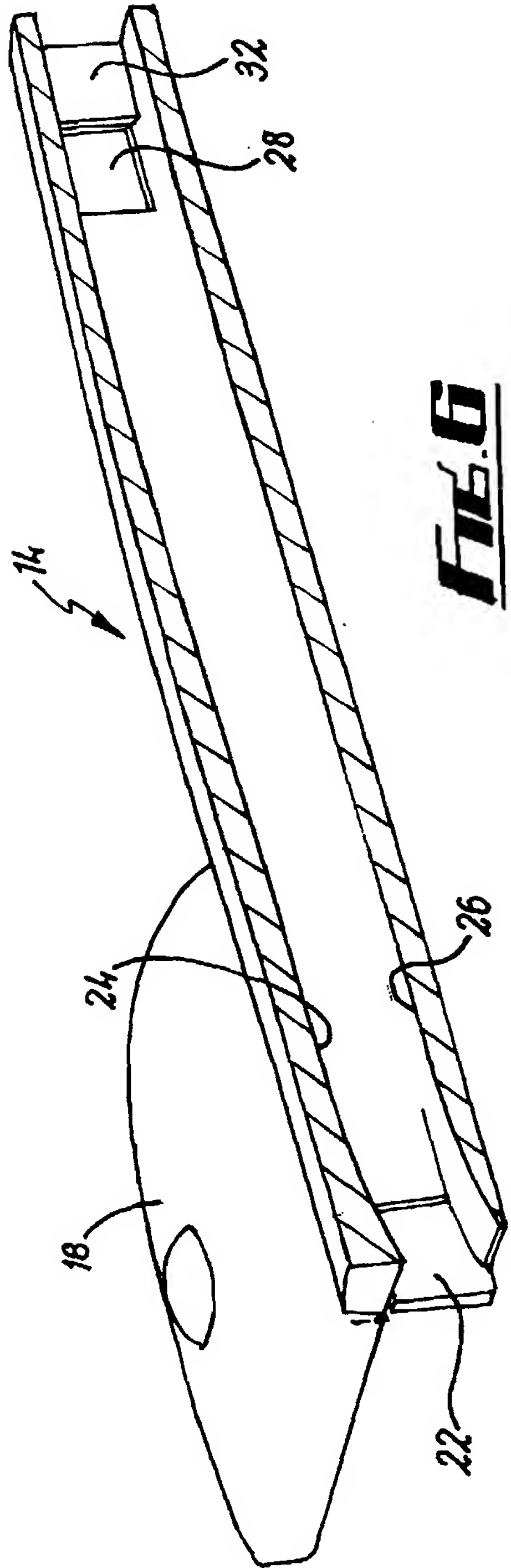
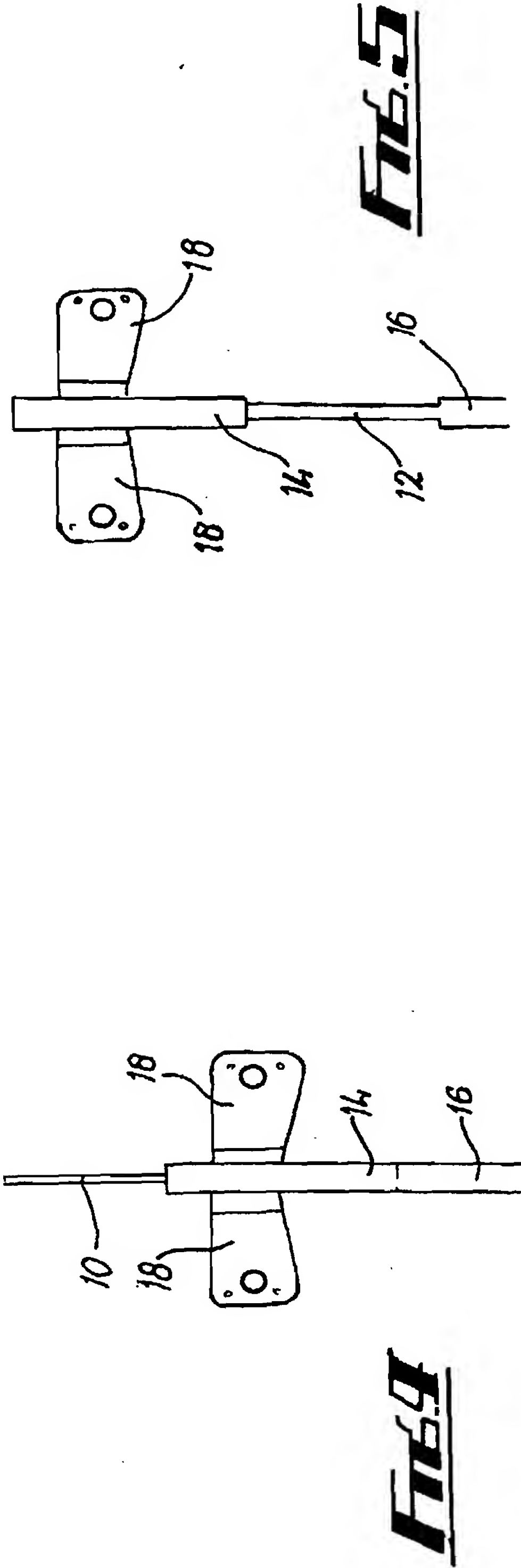
**Fig. 2**



**Fig. 3**

24 48 02

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## CANNULA DEVICE

This invention concerns a cannula device of the kind (hereinafter called "of the kind referred to") comprising a housing, a needle-mounting hub which is axially slidable in the housing and a flexible tube extending from the shield and in fluid communication with the needle to allow infusion and collection of fluids after the needle has been inserted venously or subcutaneously into a patient.

A device of this kind is disclosed in our prior International Patent Application No. GB00/02854. The present invention seeks to provide an improved device which involves fewer components and allows manufacturing costs to be reduced.

According to the present invention there is provided a cannula device of the kind referred to in which the needle-mounting hub is formed by a terminal portion of the flexible tubing.

The hub may be non-rotatable with respect to the housing and may, for this purpose, the terminal portion of the tubing may have an outer periphery which is designed to prevent rotation of the hub. For instance, the hub-defining terminal portion may be of non-circular configuration and may have a formation or formations which co-operate with a complementary formation or formations to prevent rotation. Such complementary formations may comprise projections engaging in keyways.

The housing and the hub may have interengageable formations which serve to locate the hub axially with respect to the housing in a needle-extended and/or a needle-retracted position.

In the retracted position, the hub may be prevented from being returned to the extended position so that the needle is accommodated wholly within the housing thereby preventing the needle being redeployed and reducing or eliminating the risk of needle stick injuries after the needle has been withdrawn from the patient.

In the extended position, the interengaging formations may be arranged in such a way that the needle is caused to project obliquely to a limited extent relative to the housing to facilitate initial puncture and vein entry.

The arrangement may be such that the resistance to disengagement of the interengaging formations is greater in the retracted position than in the extended position.

The interengaging formations may comprise a radial projection or projections on the terminal portion and at least one recess or aperture in the wall of the housing. In one embodiment of the invention, the radial projection on the terminal portion may co-operate, in the extended condition, with a recess at or adjacent the forward end of the housing and, in the retracted condition, with a deeper recess or an aperture at or adjacent the trailing end of the housing. In this way, the depth of interengagement at the retracted position may be greater than at the extended position thereby affording increased resistance to disengagement of the interengaging formations.

The flexible tubing may comprise a suitable resiliently deformable material, preferably a thermoplastic elastomer, compatible with the intended use and fluids to be conducted through the device.

The terminal portion of the flexible tubing may be shaped to form the hub, for example by laser cutting, by means of a high pressure fluid jet (e.g. water) or by thermoforming, for instance by moulding the features into the tubing while the latter is still in a malleable state following formation of the latter, e.g. by extrusion.

The housing may be provided with a blocking formation at or adjacent its forward end for blocking return of the needle to its extended position after it has been retracted following use.

There may be a window in the housing at or adjacent its rearward end and through which the hub is visible when the needle is fully retracted.

The hub and housing may be of contrasting colours.

Wings may extend from opposite sides of the housing and may be arranged in such a way that they may be pinched together to form a grip to facilitate manipulation of the needle when inserting same into a blood vessel.

The invention will now be described by way of example only with reference to the accompanying drawings, in which:

Figure 1 is a perspective view of one form of cannula device in accordance with the present invention;

Figure 2 is an enlarged view showing the cross-sectional view of the flexible tubing;

Figure 3 is a perspective view of the terminal portion of the flexible tubing;

Figures 4 and 5 are plan views showing the device in its needle-extended and needle-retracted conditions; and

Figure 6 is an enlarged longitudinal section view showing the interior of the shield.

Referring now to the drawings, it will be seen that the cannula device comprises a hollow needle 10 which extends forwardly from a needle hub 12 axially slidable within a tubular housing 14 forming a shield, the housing 14 being of non-circular configuration, e.g. of generally rectangular cross-section. The arrangement is such that the device has an extended condition as shown in Figure 4 in which the hub 12 is releasably located at the forward end of the shield 14 with the needle extended for insertion into a patient and a retracted condition as shown in Figure 5 in which the needle is held fully retracted into the interior of the shield and is thereby shielded to prevent needle stick injuries.

A flexible tube 16 is in communication with the the needle 10 and extends from the trailing end of the hub 12. Wings 18 project laterally from opposite sides of the shield 14 so that they may be pinched together to form a grip to facilitate manipulation of the needle 10 when inserting same into a patient. After insertion the wings 18 may be taped to the skin to hold the needle 10 in position.

A feature of the present invention is that the needle-mounting hub 12 is not produced as a separate component as in for instance International Patent Application No. GB00/02854; instead it is formed integrally with the flexible tube 16. To this end, the flexible tube 16 is of a resiliently deformable material such as a thermoplastic elastomer and is manufactured with a periphery that is non-circular, e.g. rectangular in cross-section as illustrated in Figure 2, and its terminal end is shaped as seen in Figures 3 and 4 (by laser cutting, high pressure water jet shaping or thermoforming for example) to produce a narrower hub section 12 conforming with the internal configuration of the shield 14 so that the hub can slide axially within the shield without undesirable rotation of the hub and hence the needle. The shaping step also involves providing the hub-defining terminal



portion with radially projecting, resiliently deformable projections in the form of lugs 20 on opposite sides at its forward end. The lumen 16A of the tube 16 provides a throughbore within the hub 12 for reception of the trailing end of the needle whereby the needle is affixed to and mounted by the hub.

In the extended condition (see Figure 4), the lugs 20 engage in respective recesses 22 at the forward end of the shield to afford some degree of resistance to hub/needle retraction. When so engaged, the lugs 20 are slightly compressed by engagement with the bases of the recesses 22. Also, the arrangement is such that, at its forward end, the hub 12 is slightly deformed to cause the needle to be deflected downwardly off-axis to a limited extent relative to the major central axis of the shield. In this way, the needle projects obliquely to facilitate entry into skin at a comfortable angle. For this purpose, in the illustrated embodiment the upper and lower walls 24, 26 of the shield 14 are provided with a downwardly curved contour in the vicinity of the recesses 22.

Retraction of the hub and hence the needle is effected by pulling the flexible tube 16 in the rearward direction so that the lugs 20, by virtue of their inherent flexibility (and possibly by virtue of flexibility of the shield material), ride up and out of the recesses 22. The hub is then withdrawn rearwardly by pulling the tube 16 until the lugs 20 register with apertures 28 provided in the shield side walls adjacent the trailing end of the latter. During travel along the shield, the lugs 20 are further compressed relative to the extent of compression that prevailed when they engaged with the recesses 22. In the retracted condition (see Figure 5), the lugs 20 can fully relax and project radially to a greater extent than is the case when they are engaged with the recesses 22. In this manner, the lugs 20 then offer greater resistance to forwardly directed displacement thereof from the apertures 28 than that offered when they are engaged with the recesses 22. Increased thickness side wall sections 32 serve to prevent the hub being pulled out of the shield 14.



The effort required to disengage the lugs 20 from the recesses 22 will typically be relatively low so that the user can readily retract the needle when desired, i.e. prior to releasing the device from the patient. On the other hand, the force required to disengage the lugs 20 from the apertures 28 will be substantially greater so that, for all practical purposes, the needle cannot be returned to the extended position once it has been retracted thereby locking the needle against redeployment after it has been used. If desired, the shield 12 may include blocking means in the form of a lip or flange (not shown) at the forward end thereof to block the needle once retracted.

One of the walls, usually the top wall, of the shield 14 may be provided with an aperture forming a window (not shown) at the rearward end of the shield and through which the needle hub 12, which may be coloured to contrast with the shield 14, will be readily visible when the needle 10 is fully retracted to enable an operator to verify that this is so.

It will be appreciated that it is not intended to limit the invention to the above example only, many variations, such as might readily occur to one skilled in the art, being possible.

## CLAIMS

1. A cannula device comprising a housing, a needle-mounting hub which is  
5 axially slidable in the housing and a flexible tube extending from the housing and in fluid communication with the needle to allow infusion and collection of fluids, the needle-mounting hub being formed by a terminal portion of the flexible tubing.
2. A device as claimed in Claim 1 in which the hub is non-rotatable with respect  
10 to the housing.
3. A device as claimed in Claim 1 or 2 in which the terminal portion of the tubing has an outer periphery which is designed to prevent rotation of the hub.
- 15 4. A device as claimed in any one of the preceding claims in which the housing and the hub have interengageable formations which serve to locate the hub axially with respect to the housing in a needle-extended and/or a needle-retracted position.
5. A device as claimed in Claim 4 in which in the retracted position, the hub is  
20 prevented from being returned to the extended position so that the needle is accommodated wholly within the housing.
6. A device as claimed in Claim 4 or 5 in which in the extended position, the interengaging formations are arranged in such a way that the needle is caused to project  
25 obliquely to a limited extent relative to the housing to facilitate initial puncture and vein entry.

7. A device as claimed in Claim 4, 5 or 6 in which the arrangement is such that the resistance to disengagement of the interengaging formations is greater in the retracted position than in the extended position.

5 8. A device as claimed in any one of Claims 4 to 7 in which the interengaging formations comprise a radial projection or projections on the terminal portion and at least one recess or aperture in the wall of the housing.

10 9. A device as claimed in Claim 8 in which the radial projection on the terminal portion co-operates, in the extended condition, with a recess at or adjacent the forward end of the housing and, in the retracted condition, with a deeper recess or an aperture at or adjacent the trailing end of the housing.

15 10. A device as claimed in any one of the preceding claims in which the flexible tubing comprises a resiliently deformable material.

11. A device as claimed in Claim 10 in which the flexible tubing comprises a thermoplastic elastomer.

20 12. A device as claimed in any one of the preceding claims in which the housing is provided with a blocking formation at or adjacent its forward end for blocking return of the needle to its extended position after it has been retracted following use.

25 13. A device as claimed in any one of the preceding claims in which there is a window in the housing at or adjacent its rearward end and through which the hub is visible when the needle is fully retracted.

14. A device as claimed in any one of the preceding claims in which the hub and housing are of contrasting colours.

15. A device as claimed in any one of the preceding claims in which wings extend  
5 from opposite sides of the housing and are arranged in such a way that they can be pinched together to form a grip to facilitate manipulation of the needle when inserting same into a blood vessel.

16. A cannula device substantially as hereinbefore described with reference to,  
10 and as shown in, the accompanying drawings.



INVESTOR IN PEOPLE

**Application No:** GB 0111931.2  
**Claims searched:** 1-16

**Examiner:** Dr. Simon Grand  
**Date of search:** 19 November 2002

## Patents Act 1977 Search Report under Section 17

### Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.T):

Int Cl (Ed.7): A61B17/34, A61M5/00, A61M25/00

Other: ONLINE :EPODOC, WPI, JAPIO

### Documents considered to be relevant:

Category	Identity of document and relevant passage	Relevant to claims
X	WO 01/08740 A1 (NMT GROUP PLC) See figs. and pages 2-5.	1-5, 7, 8 and 10-15
X	EP 0499077 A1 (BECTON DICKINSON) See figs. and col.3 l.39-col.4 l.33 and col.5 l.58-col.6 l.4.	1-6, 8, 10 and 11
X	US 5498241 (FABOZZI) See figs.	1, 4, 5, 7, 8, 10 and 11
X	US 5171231 (HEILIGER) See figs.(NB part 5)	1, 4, 5, 7, 8, 10 and 11
X	US 4941881 (MASTERS <i>et al.</i> ) See figs.	1-5, 7, 8, 10 and 11

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.